

REMARKS

Applicants hereby amend claims 30-31, 40-46 and 57. Support for the amendments can be found in the specification as originally filed. After entry of the amendments, claims 30-31 and 40-57 remain pending in the application. Applicants submit that the pending claims are allowable over the rejections set forth in the present Office Action. Accordingly, reconsideration and allowance of all pending claims is earnestly requested.

Claim Interpretation

The Examiner reasons that the failure to specify a temperature for the claimed viscosity feature is interpreted as leaving open the viscosity as a feature that can exist at any temperature. Applicants note that, as set forth in paragraph [0024] of the specification, viscosity measurements recited were obtained according to ASTM D1824-87, which, inter alia, specifies a temperature. Claims 30-31 and 41-46 are amended to specify this standard.

35 U.S.C. §112 Rejections

Claim 41-46 stand rejected under 35 U.S.C. §112, second paragraph. In particular, the Examiner states that there is insufficient antecedent basis for “the viscosity” in line 1 of claims 41-46. Applicants disagree. The failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. See MPEP 2173.05(e). In this instance, the scope of the claims would be understood by those skilled in the art because the composition only has one viscosity. Nevertheless, claims 41-46 are amended to expedite prosecution. Reconsideration and withdrawal of this rejection is earnestly requested.

35 U.S.C. §103 Rejections – Claims 30-31

Claims 30-31 stand rejected under 35 U.S.C. §103 as being unpatentable over Haslwanter et al. (U.S. Patent No. 6,565,832) in view of Sundgreen et al. (U.S. Publication No. 2002/0147232). Applicants traverse this rejection.

First, the Examiner acknowledges Haslwanter lacks the teaching of decongestant compositions comprising liposomes, but argues Sundgreen teaches that liposomes are conventional carriers and that liposomes are expected to enhance permeation of active agent into the mucosa, such as the nasal mucosa.

Applicants respectfully submit one skilled in the art would not have applied the teachings of Sundgreen to Haslwanter and that by so doing, the Examiner is using impermissible hindsight.

In *Ex Parte Rinkevich et al.* (BPAI 2007-1317), the board used KSR to reason that a skilled person would not look to a second patent to solve a problem already solved by a first patent (and by the patentee). The board wrote: “In the instant case, we conclude that a person of ordinary skill in the art *having common sense* at the time of the invention would not have reasonably looked to Wu to solve a problem already solved by Savill. Therefore, we agree with Appellants that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection.”

Because Haslwanter already discloses a permeation enhancer (EDTA), a skilled person would not look to the liposomes of Sundgreen to solve a problem already solved by the EDTA of Haslwanter. Moreover, Sundgreen discloses that liposomes are likely to enhance the penetration of “the active ingredient” into the mucosa [0605]. “The active ingredient” in Sundgreen is desglymidodrine. Desglymidodrine is a vasopressor given to patients suffering from orthostatic hypotension or stress incontinence [0009]. There is no teaching or suggestion in Sundgreen that liposomes are likely to be beneficial when used in conjunction with decongestants, such as oxymetazoline hydrochloride used in the composition of Haslwanter. Applicants submit that by reaching the conclusion that Haslwanter and Sundgreen could be combined to purportedly render Applicants’ invention obvious, the Examiner is using impermissible hindsight.

For the above reasons, Applicants respectfully request the Examiner reconsider this rejection and indicate claims 30 and 31 are allowable over Haslwanter and Sundgreen.

Next, the Examiner acknowledges Haslwanter lacks the teaching of an explicit viscosity value for the compositions, but argues Haslwanter’s compositions necessarily have a viscosity meeting the limitations of Applicants’ claims 30-31, because the amount of thickener in Haslwanter’s compositions is within the range disclosed by Applicants as corresponding to a viscosity range of about 2,500 cp to about 40,000 cp as evidenced by Applicants’ claims 40 and 41.

Applicants respectfully submit the Examiner’s argument is flawed because it assumes viscosity is only a function of the amount of thickener, when in reality, several additional factors

affect viscosity, such as for example the thickening properties of the thickener(s) and the method of preparing the composition.

As amended, claims 30 and 31 each recite “about 0.000001 to about 5.0 wt % thickener comprising one or more compounds selected from the group consisting of glycerin, carrageenan, sugar, guar gum, methylcellulose, and hydroxyethylcellulose.” While the spray composition disclosed in Haslwanter may incorporate additional rheology-modifying agents (column 4, lines 21-32), the “essential components of the composition” are, inter alia, a mixture of microcrystalline cellulose and an alkali metal carboxyalkylcellulose (column 2, lines 47-50). Apparently that mixture results in a thixotropic composition which exhibits a reduced apparent viscosity while being subjected to shear forces, but a high apparent viscosity while at rest (column 2, lines 20-23; column 4, lines 52-56). One of ordinary skill in the art appreciates that different thickeners have distinct thickening properties. In that regard, claims 30 and 31 each recite a group of thickeners selected for their distinct thickening properties.

For example, as amended, claim 30 recites “wherein the composition is a gelled matrix.” Haslwanter does not teach or suggest applying the oxymetazoline via a viscous gel.

For at least the above reasons, it cannot be said Haslwanter’s compositions necessarily have a viscosity meeting the limitations of Applicants’ claims 30-31. Applicants therefore submit these limitations are neither taught nor suggested by any combination of Haslwanter or Sundgreen.

35 U.S.C. §103 Rejections – Claims 40-57

Claims 40-57 stand rejected under 35 U.S.C. §103 as being unpatentable over Haslwanter et al. in view of Sundgreen et al. as applied to claims 30-31 above, and further in view of Bates (U.S. Patent No. 4,826,683), as evidenced by Schulte (U.S. Patent No. 4,708,783). Applicants traverse this rejection.

Claim 40 uses the transitional phrase “consisting essentially of” and in that regard limits the scope of a claim to the specified materials and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. The Examiner has looked to 4 references, and each reference alone or in combination with another reference includes additional materials that would otherwise materially affect the basic and novel characteristic(s) of the claimed

invention. In other words, no combination of the references teaches or suggests a composition “consisting essentially of” the ingredients presently recited in claim 40.

For instance, the composition in Haslwanter comprises a mixture of microcrystalline cellulose and an alkali metal carboxyalkylcellulose (column 2, lines 49-50). As noted above, different thickeners have distinct thickening properties. With regard to Sundgreen, the composition disclosed therein comprises desglymidodrine—a vasopressor given to patients suffering from orthostatic hypotension or stress incontinence—or a pharmaceutically acceptable salt thereof [0110].

Moreover, the Examiner acknowledges Haslwanter lacks the teaching of decongestant compositions comprising aloe vera, but argues Bates teaches decongestant compositions in the form of nasal spray that are designed to be applied to the nasal passages comprising aloe vera. The Examiner believes it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to modify the compositions of Haslwanter to include aloe vera because aloe vera promotes healing, as evidenced by Schulte.

While Schulte discloses that aloe vera promotes wound healing, nothing Schulte teaches or suggest, as the Examiner contends, that aloe vera is a conventional ingredient in nasal decongestants. To the contrary, Schulte likely only suggests use where healing is desired. As it relates to Haslwanter, that disclosure is directed toward a composition for application to a nasal membrane because active substances can move across the nasal membrane into the blood or circulatory system of the patient. However, there is no indication in Haslwanter that the nasal membrane needs wound healing. Therefore, a skilled artisan would not look to modify the compositions of Haslwanter to include aloe vera. Bates discloses no reason or motivation for including aloe vera in a nasal decongestant.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection as to claim 40 as well as to claims 41-57 pending in this application as being directly or indirectly dependent upon claim 40 and incorporating all the limitations thereof.

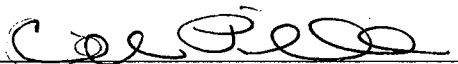
Conclusion

In view of these amendments, Applicants respectfully submit that all pending claims are now in condition for allowance and therefore respectfully request allowance of all claims. Should the Examiner find one or more of the pending claims unpatentable, the undersigned requests a call from the Examiner.

The Commissioner is hereby authorized to charge payment or credit overpayment to Deposit Account No. 19-2814 for any fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension fees pursuant to § 1.136(a). This statement does NOT authorize charge of the issue fee.

Respectfully submitted,

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